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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,505	03/15/2001	Mitchell C. Calderwood	783.5	5202

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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/809,505	<b>Applicant(s)</b> CALDERWOOD, MITCHELL C.	
	<b>Examiner</b> Kathryn Odland	<b>Art Unit</b> 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4 and 7-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment dated June 17, 2004. Claims 1, 3, 4 and 7-12 are under consideration.

### ***Response to Arguments***

1. Applicant's arguments filed June 17, 2004 have been fully considered but they are not persuasive.

Applicant argues, "Nowhere in Cunningham is there any description whatsoever about the material composition of cover 28 or that it possesses the property or capability to be sufficiently elastic so as to be expandable over and along the camera system." The examiner agrees that Cunningham is silent on the material. However, the cover (28) obviously expands along the camera system, as seen in Figure 2. Further applicant has not defined the term expandable beyond its ordinary meaning, which is to increase the scope of; enlarge; to open (something) up or out; spread out according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Moreover, Cunningham discusses plastics in the Background of the Invention Section. Plastics such as "plastic bags" as mentioned by Cunningham are certainly flexible and have a hardness value suitable for many mountings.

Applicant argues, "Further, the property or characteristic of 'being free of wrinkles' does not absolutely translate to the material being elastomeric." The examiner most certainly agrees. Cunningham discloses a wrinkle free material but is silent on the

material used. **Avni et al. was relied upon for the teaching of elastomeric sheaths for camera covers.**

The mere plethora of elastomeric material discussed by the examiner was to merely show that the ranges claimed are quite broad and many elastomers fall within the ranges. Applicant argues that the combination is improper since Avni et al. do not recite the explicit ranges claimed. However, the examiner stated that the ranges are common to many elastomers and would be within the scope of the modification and obvious to one with ordinary skill in the art. Applicant further presents irrelevant arguments about sticky materials, anti-blocking agents, etc., which are not claim limitations.

Applicant further agrees, "Avni at Col. 9, Lines 25-40 in which examples of flexible, elastic material are given to be polyethylene or silicone. These materials are used in the outer sheath of Avni..." Avni et al. was relied upon for the teaching of elastomeric materials for sheaths to shown that elastomeric sheaths are known in the camera covering art. Cunningham already discloses an optically transparent covering and Avni et al. was relied upon to show a teaching of elastomeric material use to remedy Cunningham's silence on material. Urethanes and elastomeric materials are well known in the art and it would be obvious to one with ordinary skill in the art in keeping with Cunningham's optically transparent covering to assure that it is made of an elastomeric/urethane material for the purpose of repeated mounting and dismounting and elasticity. The rejection is reiterated below.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 4, and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. in US Patent No. 4,522,196 in view of Avni et al. in US Patent No. 6,447,444.

Regarding claim 1, Cunningham et al. disclose a disposable cover and drape (28, etc.) for an endoscopic camera system having an optically clear film (40) mounted across an annular opening of a first ring segment (such as 42) and held in position at the periphery of the opening by an opposing similarly sized annular opening of a juxtaposed second ring segment (46), the ring segments and film being insertable between an endoscope (12) or elongate lens assembly for insertion into a human body cavity and a mating camera coupler (14), said first ring segment being dimensioned to cooperatively mate with and be secured to a second ring segment.

However, a second ring segment that carries an expandable flexible plastic tube having a first open end mounted to the annular opening of the second ring segment and a second open end for expanding over and substantially covering said camera system for preventing contamination of said camera system in conjunction with a surgical or exploratory procedure, said

elastomeric film having sufficient elastic memory to accept repeated mounting and de-mounting of one or more elongate lens assemblies to the mating camera coupler without tearing, cracking, splitting or rupturing such that said elastomeric film remains intact and free of wrinkles and visual distortion, where the elastomeric film has an elongation factor of between 100 percent to 1000 percent and a hardness over a range of 50 Shore A to 50 Shore D, exhibiting a resistance to tearing and abrading while retaining a clarity of optical transparency to provide maximum visual acuity has not been explicitly recited.

On the other hand, Cunningham et al. do teach an integral cover expanding over and substantially covering said camera system for preventing contamination of said camera system in conjunction with a surgical or exploratory procedure. Thus, it would be obvious to one with ordinary skill in the art to have the second ring segment carry an expandable flexible plastic tube having a first open end mounted to the annular opening of the second ring segment and a second open end for it has been held that it required only routing skill in the art to make something that was once integral separable. Further, Cunningham explicitly recites film that remains intact and free of wrinkles and visual distortion, where the while retaining clarity of optical transparency to provide maximum visual acuity, as recited in columns 3-4.

Moreover, Avni et al. teach to use elastomeric sheaths. Thus, it would be obvious to one with ordinary skill in the art and within the scope of the invention and that discussed in columns 3-4 to assure the sheath of Cunningham be made

of an elastomeric material, as taught by Avni et al., for the purpose of maintaining strength as well as clarity. Further, an elastomeric film having sufficient elastic memory to accept repeated mounting and de-mounting of one or more elongate lens assemblies to the mating camera coupler without tearing, cracking, splitting or rupturing is within the scope of the invention and would be obvious to one with ordinary skill in the art. Further, an elastomeric film that has an elongation factor of between 100 percent to 1000 percent and a hardness over a range of 50 Shore A to 50 Shore D, exhibiting a resistance to tearing and abrading although not explicitly recited is common to elastomeric materials.

Regarding claims 3 and 10, Cunningham et al. as modified by Avni et al. disclose that as applied to claims 1 and 9. Further, Avni et al. also teach an elastomeric film that **may** be made from a material selected from a group of elastomeric urethanes including polyether or polyester based aliphatic, polycaprolactate aliphatic, cycloaliphatic or aromatic, or any blend thereof, as recited in column 9, lines 25-40, for example. Thus it would be obvious to one with ordinary skill in the art and within the scope of the invention to assure the sheath of Cunningham et al. be made of a material selected from a group of elastomeric urethanes including polyether or polyester based aliphatic, polycaprolactate aliphatic, cycloaliphatic or aromatic, or any blend thereof, as taught by Avni et al. for the purpose of maintaining strength, flexibility and clarity.

Regarding claims 4 and 11, Cunningham et al. as modified by Avni et al. disclose that as applied to claims 1 and 9. Further, Avni et al. also teach an optically clear elastomeric film **may** be made from elastomeric silicones, as recited in column 9, lines 25-40, for example. Thus it would be obvious to one with ordinary skill in the art and within the scope of the invention to assure the sheath of Cunningham et al. be made of elastomeric silicones, as taught by Avni et al. for the purpose of maintaining strength, flexibility and clarity.

Regarding claims 7 and 12, Cunningham et al. as modified by Avni et al. disclose that as applied to claims 1 and 9. Further, an optically clear elastomeric film having a modulus of 1.0 to 15.0 MPa at 100% elongation and a modulus of 2.0 to 50.0 MPa at 300% elongation is also within the scope of the invention as modified.

Regarding claim 8, Cunningham et al. as modified by Avni et al. disclose that as applied to claim 1. Further, Avni et al. teach an expandable flexible plastic tube that **may** be made from any waterproof elastomeric or plastic material having a flexibility to collapse and extend in accordion-like fashion as seen in figure 6. Thus, it would be obvious to one with ordinary skill in the art to further modify the invention to Cunningham et al. to assure that the expandable flexible plastic tube that **may** be made from any waterproof elastomeric or plastic material having a



flexibility to collapse and extend in accordion-like fashion, as taught by Avni et al. for the purpose of enhanced flexibility. Moreover, a material thickness in the range between 1.0 mil to 5.0 mils is also within the scope of the invention and would be obvious to one with ordinary skill as a typical thickness.

Regarding claim 9, Cunningham et al. disclose an optically clear film (40) for use as a barrier and lens between an endoscope (12) or elongate lens assembly and a matable camera coupler (14), the elastomeric film remains intact and free of wrinkles and visual distortion is resistance to tearing and abrading while retaining a clarity of optical transparency to provide maximum visual acuity, as discussed in columns 3-4. However, Cunningham et al. do not explicitly recite an elastomeric film also having an elongation factor of between 100 percent to 1000 percent and a hardness over a range of 50 Shore A to 50 Shore D, exhibiting a resistance to tearing and abrading while retaining a clarity of optical transparency to provide maximum visual acuity having sufficient elastomeric memory to accept repeated mounting and de-mounting of one or more elongate lens assemblies to the mating camera coupler without tearing, cracking, splitting, or rupturing. On the other hand, a resistance to tearing and abrading while retaining a clarity of optical transparency to provide maximum visual acuity having sufficient elastomeric memory to accept repeated mounting and de-mounting of one or more elongate lens assemblies to the mating camera coupler without tearing, cracking, splitting, or rupturing although not explicitly recited is within the scope

of the invention and that discussed in columns 3-4 and would be obvious to one with ordinary skill in the art. Moreover, Avni et al. teach to use elastomeric sheaths. Thus, it would be obvious to one with ordinary skill in the art and within the scope of the invention and that discussed in columns 3-4 to assure the sheath of Cunningham be made of an elastomeric material, as taught by Avni et al., for the purpose of maintaining strength as well as clarity. Further, an elastomeric film having sufficient elastic memory to accept repeated mounting and de-mounting of one or more elongate lens assemblies to the mating camera coupler without tearing, cracking, splitting or rupturing is within the scope of the invention and would be obvious to one with ordinary skill in the art. Further, an elastomeric film that has an elongation factor of between 100 percent to 1000 percent and a hardness over a range of 50 Shore A to 50 Shore D, exhibiting a resistance to tearing and abrading although not explicitly recited is common to elastomeric materials.

### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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